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IN THE SUPREME COURT

OF THE UNITED STATES

OCTOBER TERM, 1991

DUANE L. ISAACS,

Petitioner,

vs.

UNITED STATES OF AMERICA,

Respondent,

APPENDIX TO PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

DUANE L. ISAACS,	) No. 90-16649
Plaintiff-Appellant,	)
v.	) D.C. No. CV-89 1553-RCB
UNITED STATES OF AMERICA,	)
Defendant-Appellee.	)MEMORANDUM*

On Appeal from the United States District Court for the District of Arizona

Robert C. Broomfield, District Judge, Presiding

Submitted: May 29, 1991**

Before: HUG, KOZINSKI, and LEAVY, Circuit Judges.

Dr. Duane L. Isaacs, appearing pro se, appeals the district court's order denying Isaacs' summary judgement

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* This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

** The panel unanimously finds this case suitable for decision without oral argument. Fed. R. App. P. 34(a); 9th Circ. R. 34-4.

motion and granting summary judgment in favor of the United States in Isaacs' action challenging the constitutionality of several provisions of the Medicare statute, 42 U.S.C. § 1395j et seq. Isaacs contends that the district court erred by finding that Isaacs lacked standing to challenge the Medicare statute solely on behalf of his Medicare patients. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

We review the district court's grant of summary judgment de novo. Kruso v. International Tel. & Tel. Corp., 872 F.2d 1416, 1421 (9th Cir. 1989), cert. denied 110 S. Ct. 3217 (1990). We must determine whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law. Danning v. Miller,

922 F.2d 544,546 (9th Cir. 1991).

"Standing is a threshold question in every case before a federal court." McMichael v. County of Napa, 709 F.2d 1268,1269 (9th Cir. 1983). A determination of standing involves an analysis of "constitutional requirements and prudential considerations." Valley Forge College v. Americans United, 454 U.S. 464,471 (1982). "[A]t an irreducible minimum, Art. III requires the party who invokes the court's authority to 'show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant,'"and that the injury is redressable by the courts. Id at 472 (quoting Gladstone, Realtors v. Village of Bellwood, 441 U.S. 91,99 (1979). Prudential considerations require that "the plaintiff generally must assert his own legal rights and

interests, and cannot rest his claim to relief on the legal rights or interests of third parties." Warth v. Seldin, 422 U.S. 490,499 (1975).

There are two exceptions to the rule that a plaintiff cannot assert the rights of absent third parties. See Singleton v. Wulff, 428 U.S. 106,114 (1976). First a plaintiff can assert a third party's rights if the enjoyment of those rights is "inextricably bound up with the activity the litigant wishes to pursue," and if the plaintiff is as effective a proponent of the rights as the third party. Id at 114-15. Second, a plaintiff may assert a third party's rights if there exists a "genuine obstacle" to such assertion by the third party, such as where assertion by the third party would result in nullification of the rights. Id at 115-16.

Isaacs contends that several Medicare provisions violate the "fundamental right" of Medicare patients to "consensual medical privacy" in the doctor-patient relationship. Although Isaacs has alleged an injury in fact under Article III, he lacks standing to assert violations of the constitutional rights of his Medicare patients.[1/]

1/ In his complaint, Isaacs contends that certain provisions of the Medicare statute violate his Medicare patients' right to "consensual medical privacy." To support his Fed. R. Civ. P. 59(3e) motion for alteration of the judgment, Isaacs filed a reply brief contending that the Medicare provisions violate the first amendment by infringing on the right of Medicare patients and doctors to associate for the advancement of common beliefs, and the right of privacy in that association. The district court construed the motion as one for reconsideration and denied it on the ground that Isaacs was improperly raising his first amendment theory for the first time in the postjudgment motion. Isaacs raises his first amendment theory again in his brief on appeal. Because this theory was
(cont.next page)

The constitutional case or controversy requirement is satisfied here because it is clear that under the challenged Medicare statutes Isaacs suffers concrete injury when he does not receive payment for services to Medicare beneficiaries when such services are deemed unreasonable and unnecessary or consist of "routine foot care." See Singleton, 428 U.S. at 113. Furthermore, if the challenged Medicare provisions are found to be unconstitutional, Isaacs will benefit by receiving payment for services otherwise uncompensable under the statutes. See id.

Isaacs' constitutional challenge to the Medicare provisions is brought solely on behalf of his Medicare

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1/ (cont.) not properly raised before the district court, we do not consider it on appeal. See Villar v. Crowley Maritime Corp., 782 F.2d 1478,1483 (9th Cir. 1986).

patients. There is no indication, however, that Medicare patients' enjoyment of their alleged constitutional right to "consensual medical privacy" is "inextricably bound up" with Isaacs' practice of medicine. Moreoever, Isaacs cannot be as effective a proponent of these rights as the Medicare patients themselves because the challenged Medicare provisions appear to protect rather than harm the interests of Medicare patients. The provisions, among other things, require doctors to inform patients of services which may not be covered by Medicare, and provide for independent review of the necessity and quality of medical services. See, e.g. 42 U.S.C. §§ 1320c-3(a)(1)(B) and 1395u(1)(1)(C); Finally, there is no "genuine obstacle" to Medicare patients, themselves, asserting a right to medical privacy

in the doctor-patient relationship. Cf. NAACP v. Alabama, 357 U.S. 449,459 (1958) (plaintiff permitted to assert absent third party's right to be protected from compelled disclosure where assertion by third party would nullify right).

Thus, because there are no genuine issues of material fact and because Isaacs lacks standing to assert the constitutional rights of his Medicare patients, the district court did not err by granting summary judgment in favor of the United States. See Warth, 422 U.S. at 508-10; cf. Singleton, 428 U.S. at 117-18 (physicians permitted to assert women patients' right to abortion where privacy considerations and imminent mootness of claim would prevent women themselves from asserting right).

AFFIRMED.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

DUANE L. ISAACS,	)	
	)	
Plaintiff,	)	No. Civ 89-1553 PHX RCB
	)	
vs.	)	
	)	ORDER
UNITED STATES OF AMERICA,	)	
	)	
Defendant	)	
	)	

Plaintiff, a podiatrist practicing in Arizona, challenges several Congressionally-prescribed limitations that are imposed on Medicare payment to physicians. Plaintiff filed a motion for summary judgment and defendants have filed a cross-motion for summary judgment.

The Medicare program is divided into two parts. Part A provides insurance for hospital and related post-hospital services. 42 U.S.C. § 1395c et seq. Part B establishes a voluntary program of supplementary medical insurance covering physicians'

and other medical services. 42 U.S.C. § 1395j et seq. This case involves Part B exclusively. Under Part B, Medicare enrollees obtain health insurance benefits in return for the payment of monthly premiums. 42 U.S.C. § 1395r(b)-(c). These premiums, taken together with contributions from the federal government, make up the Federal Supplementary Medicare Insurance Trust Fund. Benefits under Part B are paid out of this Trust Fund. 42 U.S.C. § 1395t. To help administer the program and to facilitate the payment of benefits, the Secretary of Health and Human Services is authorized to enter into contracts with "carriers" which process claims for reimbursement for physicians services and maintain records of physician charges for specific localities. 42 U.S.C. § 1395u. Aetna Life Insurance Company serves as the Medicare carrier for

Arizona.

As part of the claim review process, carriers are required to make determinations as to the reasonableness and medical necessity of the services for which claims are submitted and to deny payment where those services are determined to be "not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395u(b)(3)(B); 42 U.S.C. § 1395u(1)(1)(A)(iii)(I). Peer review organizations ("PROs") are authorized to make determinations as to the reasonableness and necessity of services rendered to beneficiaries and to make determinations as to the quality of those services. Specifically, PROs are required to determine whether services rendered meet "professionally recognized standards of health care." 42 U.S.C. § 1320c-3. As part of their claims

review responsibility, carriers are required to deny payment for services that are determined by PROs to fall short of these professional standards or not to be reasonable or necessary. 42 U.S.C. § 1395u(b)(3)(B)(ii)(II); 42 U.S.C. § 1395u(1)(1)(A)(iii)(II).

An enrollee under Part B who is treated by a physician either pays the physician and then requests reimbursement from Medicare (thus holding an unassigned claim) 42 U.S.C. § 1395u(b)(3)(B)(i), or the physician may submit the claim to Medicare directly (an assigned claim). 42 U.S.C. § 1395u(b)(3)(B)(ii). In the latter case, the physician then collects from the Medicare as the assignee of the beneficiary, while billing the beneficiary for the applicable coinsurance and/or deductible amount.

For both assigned and unassigned

claims, payment for physician services covered under Part B is the "reasonable charge" for services involves, less any applicable copayment. 42 U.S.C. § 1395u(1)(a)(1)(B). The "reasonable charge" for a service is the lowest of 1) the physicians actual charge for the service, 2) the physician's "customary charge" for similar services, and 3) the "prevailing charge recognized by the carrier" based on data for similar services in the locality. 42 U.S.C. § 1395u(b)(3)(K). Under Medicare Part B, physicians who elect to become "participating physicians" agree to take assignment of all Medicare beneficiaries' claims and to accept this Medicare reasonable charge as payment in full for those claims. 42 U.S.C. § 1395u(h)(1). Non-participating physicians such as Plaintiff may accept assignments on a case-by-case basis. If, however,

the physician does not accept assignment, the beneficiary becomes liable for the bill which the physician submits directly to the beneficiary. 42 U.S.C. § 1395u(b)(3)(B)(i).

Plaintiff performs routine foot care which he contends is medically necessary and which is excluded from Medicare coverage pursuant to 42 U.S.C. § 1395y(a)(13)(C). Plaintiff has also been required to return to the Medicare program amounts paid by the program for foot care that was determined not to be reasonably necessary under 42 U.S.C. § 1395y(a)(1).

Plaintiff challenges the constitutionality of 42 U.S.C. § 1395u(b)(3)(B)(ii)(II) and (III). This section provides that Medicare will not pay for services that a PRO finds do not meet professionally recognized standards of health care,

or if the physician agrees to not bill the patient in the event the PRO finds the services unreasonable or unnecessary. Plaintiff also challenges the constitutionality of 42 U.S.C. § 1395u(1), which prohibits non-participating physicians from charging Medicare patients for services determined by a PRO to be unreasonable or unnecessary, unless the physician i) "did not know and could not reasonably have been expected to know" that such a determination might be made or ii) before such a service was performed, informed the patient that payment under Medicare Part B may not be made for the specific services and the individual has agreed to pay for that service. Plaintiff likewise challenges 42 U.S.C. § 1395pp, which is similar to § 1395u(1), but for assigned claims. Finally, Plaintiff challenges 42 U.S.C. §

1395y(a)(13)(C), which specifically excludes from coverage all "routine foot care."

SUMMARY JUDGMENT STANDARD

To grant summary judgment, this Court must find that the record clearly establishes that there exists "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R. Civ. P. 56(c). Both parties agree that no genuine issue of material fact exists here.

STANDING

Plaintiff bases his constitutional claim as to each challenged provision on a purported right to "consensual medical privacy," a right that inheres in the doctor-patient relationship. Plaintiff claims that the provisions harm Medicare beneficiaries as well as their treating physicians. Defendant argues that Plaintiff is

merely asserting the rights of his patients and that he has no independent standing on which to base this suit.

Questions of standing break down to two issues: (1) has the litigant suffered an injury in fact?; and (2) is the litigant the proper proponent of the legal rights on which he bases his suit? Singleton v. Wulff, 428 U.S. 106, 112, 96 S. Ct. 2868,2873, 49 L.Ed. 2d 826 (1976). In Singleton, the Court found that the plaintiff-physicians had suffered injury from the state laws restricting Medicare payment for abortion procedures. Id. Likewise, Plaintiff here has suffered injury from Aetna's refusal to pay for routine foot care.

The Singleton Court addressed the issue of what rights a doctor may assert. The Court specifically refused to determine whether a doctor has a constitutional right to practice

medicine, and thus did not allow the plaintiff-doctor to assert standing based on such a right. Id. at 113, 96 S.Ct. at 2874. Plaintiff does not assert his own rights as a basis for his standing before this Court. Instead, he asserts the rights of his patients to obtain benefits for medical services under federal welfare programs. See Plaintiff's Memorandum in Support of Summary Judgment (hereinafter "Plaintiff's Memorandum"), p 26.

Generally, a litigant may not assert the rights of another as the basis of his claim. See Singleton, at 114, 96 S.Ct. at 2874. Two policy reasons suggest that the holder of the rights is usually the better proponent of his own rights. First, the holder of the rights may not want them asserted, or may enjoy the rights whether the litigant wins his suit

or not. Second, the holder of the rights is usually the best proponent of those rights. He is likely to be more aggressive in defending his own rights than another would be.

There are, however, exceptions to this general rule. Two factual elements are relevant. The first element is the relationship between the litigant and the one who holds the right. When the enjoyment of the right is "inextricably bound up with" the activity the litigant wishes to pursue, the court need not worry that the outcome of the case is immaterial to the holder of the right. Id. at 115, 96 S.Ct. 2874. Also, when the relationship is such that the litigant is as effective a proponent as the holder of the right, the litigant will be granted standing. Id.

This second element involves the

third party's ability to assert his own right. Id. When there is some obstacle which prevents the holder of the right from asserting it himself, a litigant with a close relationship to him will be granted standing. Id. When assertion of the right by its holder would result in nullification of the right, such an obstacle exists. See Id. (privacy considerations would incline a woman to forego asserting her right to an abortion); NAACP v. Alabama, 357 U.S. 449, 78 S.Ct. 1163, 2 L. Ed. 2d 1488 (1958) (assertion of a right to associate by the members themselves would nullify that right at the moment of assertion).

Plaintiff contends that his practice of medicine is "inextricably bound to" the right of patients to obtain medical care, citing Doe v. Bolton, 410 U.S. 179,197, (1973), and Whalen v. Roe, 429 U.S. 589,604 (1977).

(Plaintiff's Memorandum, p. 3). Plaintiff's reliance on these abortion cases is misplaced, because they did not rest on "the right of patients to obtain needed medical care." Those cases had roots in privacy rights held by plaintiffs, not in any right to medical care. Plaintiff has not asserted privacy rights of his patients here, and has now shown that his doctor-patient relationship inextricably binds him to any rights of his patients.

Nor is Plaintiff as effective a proponent of any rights of his patients as they would be themselves. In fact, Plaintiff's interests are somewhat adverse to those of his patients. Plaintiff seeks invalidation of several provisions that afford valuable protection to Medicare beneficiaries. For example, the waiver of liability provisions of 42 U.S.C. §§ 1395u(1)

and 1395pp, requiring physicians to inform Medicare beneficiaries that Medicare will not pay for a particular service which has been determined to be not reasonable and necessary, promotes informed decision-making and protects beneficiaries for out-of-pocket costs for services for which Medicare will not make payment.

The second element is equally unconvincing in persuading the court that Plaintiff has standing to assert the rights of his patients. The patients themselves can assert their right to obtain needed medical care here without impediment. The right would not be nullified upon the filing of a suit to protect it. The privacy considerations which impeded the women's exercise of their rights in the abortion cases are absent here, because only "routine foot care" is involved, certainly not a privacy

issue. Plaintiff lacks standing to assert the rights of his patients in this case.

IT IS ORDERED denying Plaintiff's motion for summary judgment.

IT IS FURTHER ORDERED granting Defendant's cross-motion for summary judgment.

DATED this 19th day of April 1990.

(s) Robert C. Broomfield

Robert C. Broomfield
United States District Court

Copies to all parties of record

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

* * * * * * * * * * * * * *

DUANE L. ISAACS, *

Plaintiff-Appellant, * No. 90-16649

v. * D. C. No.

UNITED STATES OF AMERICA* CV-89-1553

Defendant-Appellee * RCB

* * * * * * * * * * * * * * * ORDER

[Entered 16 August 1991]

Before: HUG,KOZINSKI and LEAVY, Circuit Judges.

The petition for rehearing is denied.

[FROM P. 39 OF PETITIONER'S COMPLAINT, FILED 20 SEPTEMBER 1989]

COUNT THREE

35. The Secretary's payment methodology policies which implement 1395y(a)(13)(C) are inconsistent with the relevant statutes and regulations and are thus violative of plaintiff's, and/or his medicare-insured patients' rights under 1395, 1395pp, 1395y(a)(1) and 1320c-3 through 5; or, alternatively, 1395y(a)(13)(C) is a purely arbitrary and invidious interdiction of his/their liberty of consensual medical privacy and thus is facially violative of his/their due process rights.

[FROM P. 19 OF PETITIONER'S MEMORANDUM IN SUPPORT OF SUMMARY JUDGEMENT, FILED 25 OCTOBER 1989]

III. 42 U.S.C. 1395y(a)(13)(C), and/or the payment methodology policies delineated at sections 4120 and 2323C of The Medicare Carriers' Manual, are facially violative of due process (and 42 U.S.C. 13955) because they effect a purely arbitrary and invidiously discriminatory interdiction of the right to consensual medical privacy of doctors who perform, and enrollees who require, that medically necessary service which consists of the non-surgical reduction of corns, callouses, and toenails.

PART B MEDICARE CARRIERS' MANUAL

2323. FOOT CARE AND SUPPORTIVE DEVICES FOR THE FEET

The scope of covered foot care services is limited by excluding the following types of services under both Part

A and Part B. (See § 4120 for procedural instructions in applying foot care exclusions.

[Irrelevant passages omitted]

C. Routine Foot Care.--Routine foot care includes the cutting or removal of corns, or calluses, the trimming of nails (including mycotic nails) and other hygienic and preventive maintenance care in the realm of self-care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of both ambulatory and bedfast patients, and any services performed in the absence of localized illness, injury or symptoms involving the foot. For example, foot care such as routine soaking and application of topical medication on the physician's order between required visits to the physician is not covered. In addition, any treatment of a fungal

(mycotic) infection of the toenail is considered routine and not covered in the absence of (1) clinical evidence of mycosis of the toenail, and (2) compelling medical evidence documenting that the patient either (A) has a marked limitation of ambulation requiring active treatment of the foot, or (B) in the case of a nonambulatory patient has a condition that is likely to result in significant medical complications in the absence of such treatment.

4120.1 Application of Foot Care Exclusions to Physicians' Services. The exclusion of foot care is determined by the nature of the service (§2323). Thus, reimbursement for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

[Irrelevant passages deleted]

3. Payment may be made for routine-type foot care such as cutting or removal of corns, calluses, or nails when the patient has a systemic disease of sufficient severity that unskilled performance of such procedure would be hazardous (§ 2323C.).

(a) Claims for such routine services would show in item 7D of the SSA-1490 the complicating systemic disease. Where these services were rendered by a podiatrist this item should also include the name of the M.D. or D.O. who diagnosed the complicating condition. In those cases where active care is required, the approximate date the beneficiary was last seen by such physician must also be indicated.

b. Relatively few claims for routine-type care are anticipated considering the severity of conditions

contemplated as the basis for this exception. Claims for this type of foot care should not be paid in the absence of convincing evidence that nonprofessional performance of the service would have been hazardous for the beneficiary because of an underlying systemic disease. The mere statement of a diagnosis such as those mentioned in §2323C does not of itself indicate the severity of the condition. Where development is indicated to verify diagnos and/or severity the carrier should follow existing claims processing practices which may include review of carrier's history and medical consultation as well as physician contacts.

c. A presumption of coverage may be made by the carrier where the claim or other evidence available discloses certain physical and/or clinical findings consistent with

the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption the following findings are pertinent:

Class A Findings: **Nontraumatic amputation of foot or integral skeletal portion thereof**

Class B Findings: Absent posterior tibial pulse; Advanced trophic changes as (three required): hair growth (decrease or absence);nail changes (thickening);pigmentary changes (discoloration);skin texture (thin,shiny);skin color (rubor or redness); Absent dorsalis pedis pulse

Class C Findings: Claudication; Temperature changes (e.g.,cold feet; Edema; Paresthesias (abnormal spontaneous sensations in the feet); Burning

The presumption of coverage may be

applied when the physician rendering the routine foot care has identified: (1) a Class A finding; (2) two of the Class B findings; or (3) one Class B and two Class C findings. Cases evidencing findings falling short of these alternatives may involve podiatric treatment that may constitute covered care and should be reviewed by the carrier's medical staff and developed as necessary.

For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, the carrier may deem the active care requirement met if the claim or other evidence available discloses that the patient has seen an M.D. or D.O. for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services or had come under such care shortly

after the services were furnished usually as a result of a referral.

d. Podiatry claims involving routine foot care services, including those for which a presumption of coverage can be made, should be verified on a sample basis, to assure that proper program payments are made for this normally non-covered service. This development should verify that the MD or DO identified on the claim has in fact diagnosed the complicating condition, agrees with the podiatrist's statement as to the severity of the condition, and where required, has been actively treating the patient for the condition (§2323C). Verification may be accomplished through telephone calls, form letters, questionnaires, or any other effective method of contacting physicians.

[Irrelevant passages deleted]

SECTIONS 1862(a)(1)(A) AND 1862(a)(13)(C) OF THE SOCIAL SECURITY ACT, CODIFIED AS 42 U.S.C. 1395y(a)(1)(A) AND 1395y(a)(13)(C), RESPECTIVELY

1395y. Exclusions from coverage

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B of this subchapter for any expenses incurred for items or services--

(1) (A) which, except for items and services described in subparagraph (B),(C), or (D), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

[Irrelevant passages deleted]

(13) where such expenses are for

(C) routine foot care including

the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

SECTION 1842(1) OF THE SOCIAL SECURITY ACT CODIFIED AS 42 U.S.C. 1395u(1)

(1) Unassigned billing of services determined to be medically unnecessary by a carrier

(1)(A) Subject to subparagraph (C) if--

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part.

(ii) payment for such service is not accepted on an assignment-related basis.

(iii)(I) a carrier determines under this part or a peer review organization determines

under Part B of subchapter XI of this chapter that payment may not be made by reason of section 1395y(a)(1) of this title because a service otherwise covered under this subchapter is not reasonable and necessary under the standards described in that section or (II) payment under this subchapter for such services is denied under section 1320c-3(a)(2) of this title by reason of a determination under section 1320c-3(a)(1)(B) of this title, and

(iv) the physician has collected any amounts for such services, the physician shall refund on a timely basis to the individual

(and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if--

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse

determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (a)(iii)(I) if--

(i) the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1395y(a)(1) of this title, or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that

service.

(2) Each carrier with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of subchapter XI of this chapter shall send any notice of denial of payment for physicians' services based on section 1395y(a)(1) of this title and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

Prepared by: Duane L. Isaacs, D.P.M.